



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



AUG 1 2003

Dr. Inés Triay, Manager
Carlsbad Field Office
U.S. Department of Energy
P.O. Box 3090
Carlsbad, NM 88221-3090



OFFICE OF
AIR AND RADIATION

Dear Dr. Triay:

I am responding to the Department of Energy's (DOE's) proposal of April 30, 2003, regarding characterization of remote-handled (RH) transuranic (TRU) waste for disposal at the Waste Isolation Pilot Plant (WIPP). The DOE provided documents describing the RH TRU waste characterization program and waste characterization program implementation plan (WCPIP). The April 30 proposal updates draft plans submitted to EPA in December 2002 and incorporates revisions in response to EPA comments provided to DOE in March 2003. (See EPA Letter dated March 28, 2003 in the EPA Air Docket II-B3-54.)

The current proposal addresses many of our comments. On a broad level, we believe that the RH characterization plan and WCPIP now provide an adequate general framework for conducting RH waste characterization. The waste characterization program document explains how and why the proposed RH characterization differs from the scheme that has been implemented at DOE sites to characterize contact-handled (CH) TRU waste for disposal at WIPP. The plan provides an overview of the methods and corresponding characterization objectives for RH waste. The WCPIP provides additional detail on some aspects of waste characterization processes and describes data collection and management. Collectively, these documents describe a waste characterization program that, if properly implemented, we expect would be sufficient, given the particular operational and technical considerations of RH waste compared to CH waste.

However, the information provided is not sufficient for us to understand clearly how the system could be readily implemented at DOE sites and whether it would be adequate to achieve the stated data quality objectives and acceptance criteria. In particular, in order to confirm adequate RH waste characterization at a site, we would need to understand in detail how the characterization techniques address quality assurance objectives (QAOs) for each of the data quality objectives (DQOs) derived from the regulatory requirements at 40 CFR 194.24. (QAOs describe quantitative and/or qualitative limits that data must meet with regard to data quality characteristics, including precision, accuracy, representativeness, completeness, and comparability.) The documents you provided did not include detailed requirements for fulfilling QAOs and related technical elements. For example, the WCPIP contained QAOs for some of the components of the dose-to-curies (DTC) method but did not include them for other DTC

030802



components such as modeling and drum sampling. Similar concerns were identified relative to other waste characterization methods (such as destructive assay or statistical sampling for nondestructive assay) unique to RH waste.

With the understanding that such information is a prerequisite to allowing RH disposal in WIPP from waste generator sites, there are two main options for providing such information. The first is to expand the documents you have provided—with particular attention to the WCPIP—to include QAO-related information and detailed procedures for all technical elements of the waste characterization methods proposed for RH characterization. This would be analogous to the approach used in the well-established CH characterization scheme with which EPA, DOE's Carlsbad Field Office, DOE sites, and the public have considerable experience. It would provide a degree of standardization among the generator sites, which simplifies implementation and encourages consistency across the DOE waste complex.

A second approach would be to provide this information through site-specific waste characterization program plans. This option would provide sites flexibility to develop tailored waste characterization programs, in consideration of the fact that RH waste streams—and associated data availability and quality—vary widely among sites. However, this approach leaves much greater uncertainty at the present about whether and how sites can effectively implement RH characterization programs. If DOE elects this approach, EPA would most likely constrain the uncertainty by imposing additional controls on site approvals for RH waste characterization. Like for CH waste, we would continue to inspect sites (under Section 194.8 of the WIPP Compliance Criteria) to verify proper implementation of RH waste characterization processes. In addition, we would probably require additional (and earlier) notification and approval of site-specific RH characterization program plans and procedures; this site-specific document review and approval by EPA would be required prior to allowing the implementation of any RH waste characterization measures at a site.

The enclosures to this letter provide comments and describe additional information we believe would be necessary to fully implement and evaluate RH waste characterization at generator sites, based on our review of the April 20, 2003, proposal. We generated comments in response to the question: Using the proposed approach and the WCPIP, can DOE sites adequately demonstrate their RH WC capabilities and compliance with the regulatory requirements? Enclosure A is the narrative of our general comments and those specific to RH waste characterization processes, considering worker health and safety. Enclosure B tabulates information presented in Enclosure A, identifying what additional information must be provided—in either the WCPIP or subsequent site-specific documents—regarding site implementation.

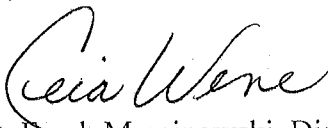
Once we receive the additional information, we will evaluate the proposal to determine whether it constitutes an adequate waste characterization program. If DOE elects to defer a significant amount of technical detail to site-specific documents (the second option discussed above), we expect that you will delineate clearly what documents the sites will be required to develop to address these issues, and how the presentation of this information will be organized to facilitate EPA's review. We also plan to observe a demonstration of RH waste characterization the week of August 4 at the Los Alamos National Laboratory. The results of this demonstration

will also inform our decision about the program's adequacy and how its implementation might work in practice. Before making a final determination, we expect to solicit public input on our technical evaluation and decision. We have placed DOE's submissions related to RH waste, as well as EPA's responses, in our public dockets.

Finally, we understand, based on our current performance assessment (PA) activities preparing for WIPP recertification, that DOE is revising the RH inventory, and the updated information would be incorporated in the new PA. We believe that this is an appropriate mechanism for evaluating such information and will review DOE's RH inventory estimates and its impact on the PA independently when we receive such information.

If you have questions regarding our comments, please contact Rajani Joglekar at (202) 564-7734.

Sincerely,


for Frank Marcinowski, Director
Radiation Protection Division

Enclosures

cc:

Lynne Smith, DOE HQ
Matthew Silva, EEG
Steve Zappe, NMED
EPA Docket

Enclosure A

The U.S. Environmental Protection Agency (EPA) has examined the Department of Energy (DOE)'s RH Proposal of April 30, 2003 to answer a specific question: ***Can RH sites adequately characterize their waste by implementing the Proposed Plan and demonstrate to EPA their waste characterization capabilities?*** Based on our review we have determined that while the proposal provides an adequate general framework for conducting RH waste characterization (WC), it still lacks some key elements necessary to demonstrate adequate RH waste characterization in order to meet Condition 3 of the WIPP Certification Decision.

Below we discuss additional information necessary regarding the implementation of the waste characterization program for our evaluation. Enclosure B tabulates information contained in Enclosure A. Hence, Enclosures A and B must both be considered to determine what information EPA is seeking from DOE or the sites. In this Enclosure, we discuss some of the components of the proposed RH approach that are considered appropriate and acceptable, as well as those components requiring DOE to revise the WCHIP or require each RH site to address in developing site-specific WC procedures for EPA approval prior to their implementation.

Below are EPA's general comments on each of the characterization methods discussed in the proposal.

1. Overall RH Waste Characterization Process

a. *RH-CH Program Equivalency*: The DOE proposed to characterize all RH waste using acceptable knowledge (AK) primarily to address ALARA issues – the goal of minimizing workers' exposure to radiation. This AK would then be qualified by confirmation, QA program equivalency demonstration, or peer review. [DOE does not seek the use of corroborating data to qualify AK, and without additional information, EPA would expect to explicitly exclude corroborating data from any approval; see Item 1.8. in Enclosure B] DOE asserts that this approach is the same as is currently being used for contact-handled (CH) waste characterization. However, we disagree with this assertion. In the case of the CH waste characterization program, DOE has implemented, and EPA has accepted, that sites generate 100% measurement data for all CH waste. While AK-NDA comparisons are made in the CH program with respect to confirmation of AK via measurements, it has not been performed at a rigorous level using established QAOs. For CH, sites report actual radionuclide concentration data from the NDA in the WIPP Waste Information System (WWIS) database, making AK-NDA comparison less critical and of a supplementary nature. Therefore, practical implementation of the CH approach has *not* been the same as that proposed for RH.

DOE contends that 40 CFR 194.22 allows the use of the AK qualification approach for WC activities. While in principle this is acceptable, the application of these

methods to waste characterization activities entails significantly different considerations compared to other data and activities addressed in Section 194.22. Thus, it may not be legitimate or practical to apply all these methods to waste characterization in practice. It should also be noted that the quality assurance (QA) requirements in 40 CFR 194.22 (Condition 2 of the WIPP Certification Decision) necessitates that data used to demonstrate compliance must also be assessed for their quality characteristics, including precision, accuracy, representativeness, completeness, and comparability. Any AK data used for characterization must meet defined standards for these quality assurance characteristics.

Also, the requirement to qualify AK data is separate from EPA's requirement that DOE develop a "system of controls" (i.e., WC program) that "will continue to be implemented to confirm... waste component[s]". Section 194.24(c)(4) states that the system of controls *shall* include "measurement; sampling; chain of custody records; record keeping systems; waste loading schemes used; and other documentation." The use of AK (process knowledge) as the major "system of controls" is not necessarily congruent with the statement that the system of controls *shall* include measurements, etc.

Additionally, DOE proposes *not* to provide a Confirmatory Testing Plan unless a "non-standard" method is used, stating that dose-to-curie (DTC), destructive analysis (DA), etc., are standard methods. We view standard methods as those that have been applied and consistently demonstrated in the CH program, and for which detailed technical elements and procedures have been specified; 100% nondestructive assay (NDA) and 100% nondestructive evaluation (NDE) are standard (e.g., Items 1.2 and 1.iii in Enclosure B). This distinction is important because we do not rigorously "confirm" NDA data per se under the current CH program since all CH waste containers undergo complete NDA. We compare the CH AK record with NDA and reconcile the CH AK record, but typically require that the sites measurement data be included in the WWIS as the characterization mechanism, not AK (there have been a very few exceptions where AK data were allowed for some information, but individual container measurement data were also obtained). If sites choose to use non-standard methods, as viewed by EPA, to characterize RH waste containers then, as stated in Items 1.2, 1.ii, and 1.iii in Enclosure B, sites must develop Confirmatory Testing Plans for approval by EPA. As with the CH Program, EPA requires that detailed implementation procedures be prepared for all confirmation techniques, whether considered standard or non-standard.

To conclude, we believe that the process proposed by DOE is not the same as that currently implemented by DOE and accepted by EPA for the CH program because we rely on measurements (e.g., 100% NDA) as the primary system of controls for determining the radiological characteristics of transuranic (TRU) waste. The process that DOE seeks approval from with respect to RH waste is significantly different from the CH program in place, though there are many common technical elements and considerations.

b. *The RH Proposal as a General Framework and Early EPA RH Program*

Involvement: The DOE appeared to adequately address most of the comments offered by EPA on the December 2002 RH Submission. As a result, we believe that the WCPIP has been improved to provide a better general framework for conducting RH waste characterization. However, the WCPIP does not include adequate detail commensurate with the CH-WAC in certain areas such as waste characterization (e.g., see Items 1.5, and 1.vi in Enclosure B); element-specific quality assurance objectives (QAOs) and data quality objectives (DQOs) (e.g., see Items 1.1 in Enclosure B). Instead, DOE expects that sites would use the general framework established in the RH Proposal to develop the necessary site-specific technical WC documents. This approach, however, has its limitations. For example, the RH program complicates the attainment of the QA requirements of precision, accuracy, representativeness, completeness, and comparability, particularly in the areas of "non standard" waste characterization methods [i.e., those WC methods that deviate from the CH program standard of 100% NDA and nondestructive examination (NDE)]. Additionally, the RH program does not include specific technical criteria and QA requirements for other WC elements, namely dose-to-curie (DTC) and destructive assay (DA), perhaps because these criteria/requirements could vary between sites. We understand that DOE may wish to retain characterization flexibility for sites and, as such, has not specified criteria, etc., common to the CH program, instead advocating their development on a site-specific basis. Therefore, while the document provides an adequate general framework, it is not possible for sites to directly implement many elements of the WCPIP because they need to develop site-specific criteria, QAOs, etc.

EPA can assess a site's RH waste characterization capabilities only if these more detailed requirements, captured in documents such as the Site Specific Detailed Assessment Plans, Confirmatory Testing Plans, QAPjPs, and SOPs, are provided to EPA for review. Early approval by EPA of RH waste characterization activities would help limit needless activities that ultimately might not be approved by EPA, thus reducing worker exposure to radiation while performing characterization activities that do not meet EPA approval, or by performing unnecessary work in the first place. Item 1.2 in Enclosure B describes the information that DOE and each site should provide, for EPA approval, in certain programmatic (i.e., revised WCPIP) and site-specific RH documentation prior to its implementation.

To conclude, the WCPIP does not provide sufficiently detailed requirements and specifications to ensure that characterization will be comparable between sites, that sites will implement appropriate characterization options, and/or that the characterization options chosen by a site are adequately implemented. To ensure that appropriate characterization takes place (including acceptable implementation of general RH requirements), early review and approval of DOE and site-developed documentation and programs by EPA is likely to be necessary.

c. *Elements and Requirements Excluded from the RH Proposal:* The WCPIP does not address many of the elements covered by the CH program, including data validation/verification, documentation requirements, etc. Therefore, Items 1.6 and 1.vii in Enclosure B require that RH sites incorporate CH program mandates and EPA-approved practices for any technical elements not explicitly included in the RH proposal. In some cases, EPA may determine that more (or less) rigorous requirements may be necessary under the RH program than currently implemented under the CH program (e.g., Item 1.7 in Enclosure B), but because DOE did not address all elements in the RH proposal, EPA requires this information to ensure, at a minimum, that all technical elements are addressed adequately. In addition, EPA mandates the preparation of Detailed Assessment Plans when additional AK is sought through measurement. EPA also requires the preparation of Confirmatory Testing Plan for all non-standard confirmatory methods; both must be provided to EPA for review and approval prior to implementation.

d. *Load Management and Overpacking:* In light of DOE's current use of ten drum overpacks (TDOP) in the CH program, we are compelled to clarify the use of overpacks as payload containers (see Items 1.3. and 1.v in Enclosure B). For RH, our working assumption under the proposal would be that an overpack can be used only when surface contamination is discovered on an individual drum/canister; that is, overpacking would not be used as a method for achieving compliance with the TRU waste threshold or the concentration limits on RH waste. If DOE plans to use overpacks for such purposes, the proposal must be revised to describe such plans. Mathematical averaging or manipulation of data from measured containers within larger containers must first be approved by EPA on a site-specific basis.

2. Non-Destructive Assay

The NDA program proposed as part of the RH WCPIP can be implemented in a manner that is essentially identical to that used in the CH program, including the commitment to perform 100% NDA. Departures from performing NDA on each container would be considered non-standard and require preparation of a Confirmatory Testing Plan that is provided to EPA for review and approval (Items 2.1 and 2.iii in Enclosure B). A major departure from the CH NDA program is the absence of the performance demonstration program (PDP) in the RH program. The EPA inspectors currently do not rely on results from the CH PDP to determine the acceptability of any specific CH program, so the removal of the PDP from the RH program will not necessarily hinder the EPA inspection of NDA process. The absence of the PDP, however, will require EPA to assess the rigor and validity of any other intercomparison, mockup tests, or other standards-based testing done on the systems to ensure they are capable of performing over the expected analysis ranges. Approval of any RH NDA program will require close attention to some specific technical details that are not typical problems in the CH program, such as accounting for deadtime, shielding, and high scattering signals. If the DOE site uses NDA in non-standard manners (i.e., to obtain additional AK data or in a less than 100 percent NDA confirmatory action), according to

Item 1.2 in Enclosure B, we would expect the site to involve EPA early in the process to ensure the technical validity of systems used and that the approach comports with the intended use of the data.

3. Dose to Curie (DTC)

The WCPIP, including Attachment C, provides a set of general requirements and a description of the Dose-to-Curie (DTC) method to estimate the activity of the radionuclides present in the RH waste. This revision of the WCPIP addresses many of EPA's earlier comments, and the most important issues relating to the DTC method are discussed, or at least mentioned, in Attachment C. DTC could, in theory, provide the information necessary to characterize the radiological constituents of RH waste, and the WCPIP could provide useful guidance to generator sites that choose to use the DTC method. However, Attachment C does not provide objective criteria by which one could assess the application of the DTC method as part of an EPA inspection because the use and applicability of DTC could vary based on waste, site, AK data quality, etc. Item 3 in Enclosure B identifies some of EPA's concerns in this regard.

In the CH program, waste characterization inspections of NDA systems are based largely on CCA and CH waste acceptance criteria (WAC), which provide a common understanding between the site, CBFO, and EPA about what is expected. EPA waste characterization inspections for an RH program using the DTC method, based solely on the WCPIP, would have to rely on higher level documents, yet-to-be developed site-specific documents/procedures, and expert opinion. As such, EPA's RH inspections would likely be more subjective than the CH inspections presently conducted. To achieve objectivity in the EPA inspection, Item 1 in Enclosure B addresses information that a site intending to pursue DTC methodology for characterization or confirmation would need to provide in DTC documents prior to their implementation for EPA review and approval.

Also, Attachment C of the WCPIP differs significantly from Attachment A in the CH-WAC. Attachment C does not require sites to demonstrate that an NDA system is capable of meeting the DQOs for accuracy, precision, completeness, representativeness, and comparability. Attachment C of the WCPIP provides only a set of steps that must be completed to use the DTC method. Therefore, Items 3.1- 3.6 in Enclosure B request revision of the WCPIP to address several technical considerations not adequately detailed in the current WCPIP. For example, Item 3.1 suggests that an RH site that uses the DTC method to derive results should meet the same data quality objectives for accuracy, precision, representativeness, completeness, and comparability that apply to NDA systems as part of the existing CH program. Note that detection limits and total measurement uncertainty (TMU) determination are necessary for DTC as separate requirements as they are for any other NDA method.

Additionally, EPA believes that 40 CFR 194.23 applies to the modeling required as part of the DTC method. This includes both isotope generation and depletion, and

container self-shielding. Therefore, as Item 3.2 in Enclosure B, DOE must develop requirements addressing §194.23 with respect to DTC-related modeling; upon EPA approval, these will be included in the WCPIP and Attachment C.

To conclude, the acceptability of the site-specific DTC plans and procedures will be determined by evaluating the technical quality of the methods to be implemented, comparing them to EPA guidance for development of QAOs, and verifying proper flowdown of higher tier requirements such as those in the WCPIP.

4. Destructive Assay

The WCPIP lacks Site-Specific Detailed Assessment Plans or Confirmatory Testing Plans/Sampling Plans (if applicable), which hinders EPA assessment of Destructive Assay (DA), if this approach is to be used. See Item 1.2 in Enclosure B. Also, given a lack of program requirements and criteria for DA in the WCPIP, EPA's process to review and approve program implementation may be more subjective in nature using criteria and/or imposing additional requirements not proposed by DOE. Item 4.1 in Enclosure B deals with specific DA-related technical elements missing from the current WCPIP. In the absence of specific criteria in the WCPIP, EPA would be required to assess this information on a site-by-site basis, and EPA would also have to ensure that this determination was implemented reasonably consistently between sites. EPA review and approval of site-specific Detailed Assessment Plans and Confirmatory Testing Plans would likely be necessary prior to DOE conducting RH waste characterization by DA. Also, for DA, the Confirmatory Testing Plan/Sampling Plans must include programmatic elements such as allowable error, data validation criteria, data useability criteria, or data assessment specifications.

5. Acceptable Knowledge

The acceptable knowledge (AK) process proposed is similar to that implemented under the CH program, except that sites are required to collect all possible drum/container-specific data and that qualification of AK will be done by confirmation, determination of QA equivalency, or peer review. However, the AK program must be more rigorous than that of the CH program, particularly with respect to how the AK confirmation process will take place and how it will be determined whether confirmation has been achieved. The DOE indicates that it may perform some of this type of calculation in the Confirmatory Testing Plans, but does not propose a consistent methodology to quantitatively assess confirmation. DOE must revise the WCPIP Attachment A to include this information (see Item 5.1 in Enclosure B). The revision must provide specifically how the AK data is to be "confirmed" using the confirmatory test data, including accuracy requirements and other applicable comparative tests to ensure that AK data are compared consistently and quantitatively with measured information. This will ensure that confirmation is performed consistently, defensibly, accurately, and appropriately across the DOE complex. For those RH programs that

mimic the CH program, we expect that the reconciliation would take place as is currently performed for the CH program (that is, the measured data takes precedence and is the source of data entered in the WIPP Waste Information System, WWIS).

6. WWIS

DOE must specify how RH data will be populated in the WWIS. This information must be included in a revision to the WCPIP or in Site Certification/QAPjPs, as appropriate, and this population methodology must be consistent between sites and methodologies. The expectation is that any modification to WWIS fields or input decision criteria to accommodate RH waste characterization information would need to be documented and be approved by EPA prior to implementation of the RH program. The current WWIS and WWIS Users Guide do not address the specific data needs that may occur in conjunction with the collection and presentation of RH characterization information. DOE must identify the additional data needs for the RH characterization program, modify the WWIS and WWIS Users Guide to accommodate the additional data needs, and provide this additional information to EPA (Item 6.1 in Enclosure B).

7. Conclusions

Upon review of the WCPIP, we conclude that the proposed plan provides a generalized framework for sites to follow, but lacks significant detail to be enacted as a stand-alone characterization scheme analogous to the CH program. This is because the DOE seeks inherent flexibility in developing and implementing processes at RH waste sites, and hence does not want to be too prescriptive in its RH waste characterization program proposal. We can accept this generalized proposal for RH waste characterization provided to EPA on April 30, 2003, only if DOE and/or sites provide additional information specified herein and summarized in Enclosure B, including several items mandating that RH waste sites develop appropriate documentation for non-standard characterization processes or measurement-related additional AK data acquisition (presented in Detailed Assessment Plans). This will ensure that characterization processes are not performed that EPA ultimately cannot approve, unnecessarily exposing individuals to radiation. That is, our concerns include the ALARA issue, in that we believe sites must get EPA approval before proceeding along a path to ensure that they do not unnecessarily expose individuals during waste characterization.

Enclosure B
Summary of Comments Suggesting Changes to WCPJP and Seeking Information from DOE and RH Sites

WC Elements	Revise the WCPJP or site specific documents to include the following:	Information from DOE ¹	Information from RH Waste Sites in site-specific documents
1: General	<p>1. To require that all RH Certification Plans also include:</p> <ul style="list-style-type: none"> mechanisms for assessing DQOs; and justification for the selected confirmation pathways for each DQO <p>2. To require preparation and provision, as applicable, the Detailed Assessment Plans, Confirmatory Testing Plans, Peer Review Plans, and QAPD crosswalk/referenced Plans, or other plans developed to support the confirmation process; these must be provided, by RH sites, to EPA for review and approval prior to implementation. Also revise to recognize EPA's determination of "standard" techniques. State that any implementation of plans prior to obtaining EPA approval will be done so at risk by the DOE sites, and EPA cannot be held accountable for any actions occurring prior to EPA approval that may be contrary to that approval.</p> <p>3. To reflect the following:</p>	<p>a. Provide a revised WCPJP. Specify information required by EPA that will be addressed in site-specific documents.</p> <p>b. Provide the Average container material of construction weights@ and as appropriate, use this information in any PA calculations</p> <p>c. Provide estimates of S5000, S4000, and S3000 wastes to support an assumption that 49% of the container would contain plastic</p>	<p>i. Reflect all changes in the WCPJP within site-specific procedures in and/or in relevant plans, including but not limited to Items 1.1 through 6.1 (Also refer to Enclosure A)</p> <p>ii. Develop, for EPA review/approval, Data Acquisition Plans if additional AK information is collected that obtains this data through measurement (i.e. NDA, NDE, etc). Submit Data Acquisition Plans to EPA prior to implementation. Obtain EPA Approval of these plans prior to implementation.</p> <p>iii. Develop, for EPA review/approval, Confirmatory Testing Plans, Peer Review Plans, QAPD crosswalk/referenced Plans, and RH Certification Plans that address techniques or methodologies including but not limited to:</p> <ul style="list-style-type: none"> Peer Review or qualification of additional data to supplement or confirm AK; or using Anon.standard@ AK confirmation method with nonstandard being anything other than 100% NDA and/or 100% NDE <p>Submit all above plans to EPA prior to implementation. Obtain EPA approval of these plans prior to implementation.</p> <p>iv. Show that qualification data generated complies with the QAOs at 194.22 (precision, accuracy, representativeness, comparability, and completeness)</p>

Enclosure B
Summary of Comments Suggesting Changes to WCPIP and Seeking Information from DOE and RH Sites

WC Elements	Revise the WCPIP or site specific documents to include the following:	Information from DOE ¹	Information from RH Waste Sites in site-specific documents
	<ul style="list-style-type: none"> • an overpack is used only when surface contamination is discovered on an individual drum/canister • the LWA limit of 23 Ci/liter is averaged over the canister and NOT the Apayload container[®] or an overpack • RH waste is either direct loaded into canisters or emplaced in smaller containers in the canister, with the measurement technique and waste packaging configurations reviewed and approved by EPA • Mathematical averaging or manipulation of data from measured containers within larger containers must be approved by EPA on a site-specific basis <p>4. To include a revised 10-10-All approach that does not rely solely on the presence of liquids and which includes waste stream designation, waste material parameter contents (description only), waste stream description, packaging materials, including liners, fill percent (if the</p>		<p>v. Demonstrate that all requirements pertaining to RH waste characterization, loading, and packaging are complied with including that directly loaded waste is appropriately characterized.</p> <p>vi. Attach complete Characterization Information Summary consistent with that of the CH program to the WSPF</p> <p>vii. Reflect and implement, in site procedures, the requirement that all activities specifically not addressed by the RH proposal are performed in accordance with the current CH program</p> <p>viii. Provide all applicable procedures, processes, and documents to EPA should EPA elect to audit or inspect these activities.</p> <p>ix. Inform EPA, in writing, of all measurement related characterization activities that will be performed one month before implementation</p>

Enclosure B
Summary of Comments Suggesting Changes to WCPIP and Seeking Information from DOE and RH Sites

WC Elements	Revise the WCPIP or site specific documents to include the following:	Information from DOE ¹	Information from RH Waste Sites in site-specific documents
	<p>container is used for DTC and NDA, if required), primary container contents, other significant matrix information, as identified in AK, prohibited items.</p> <p>5. To require that a Characterization Information Summary consistent with that of the CH program is prepared and attached to the WSPF</p> <p>6. To state that all activities specifically not addressed by the RH proposal are performed in accordance with the current CH program</p> <p>7. To state that EPA has retained the right to assess and approve technical elements on a site-by-site basis, and request revisions, changes, or other modifications to the RH proposal as is technically and/or regulatorily warranted</p> <p>8. To emphasize that EPA is not approving the use of corroborating data as a qualification method at this time.</p>		

Enclosure B

Summary of Comments Suggesting Changes to WCPIP and Seeking Information from DOE and RH Sites

WC Elements	Revise the WCPIP or site specific documents to include the following:	Information from DOE ¹	Information from RH Waste Sites in site-specific documents
2: NDA	1. To require calculation of TRU alpha uncertainty for all NDA, standard and non-standard. Also revise the WCPIP to require, in the site Certification Plan and/or Confirmatory Testing Plan, a method for calculating TRU alpha uncertainty on the measured container (i.e. canister or containers interior to the canister).		<p>i. Provide EPA with test results to demonstrate compliance with data quality requirements. Ensure Item 2.1 is met.</p> <p>ii. Prepare all Confirmatory Testing and/or Detailed Assessment Plans that includes how the non-standard approach still meets the program requirements for data quality.</p> <p>iii. Ensure that any non-standard use of NDA methods is introduced in the site Certification Plan and described fully in the required Confirmatory Testing/Detailed Assessment Plans, including how the non-standard approach still meets the program requirements for data quality. Prepare and provide Certification Plans, Confirmatory Testing, and Detailed Assessment Plans to EPA before implementation. Obtain EPA approval of Plan(s) prior to implementation.</p>
3: DTC	1. Quantitative DTC QAOs that address all components of the DTC methodology (i.e. modeling, sampling, dose rate measurement). These should be developed on a programmatic basis and included in the WCPIP, unless DOE can demonstrate the need for site-specific QAOs.	a. Provide written justification to EPA, for approval, if DOE determines it cannot include quantitative DTC QAOs in the WCPIP; EPA shall approve this justification.	<p>i. Prepare site specific Confirmatory Testing Plan to address DTC activities, which will include the Sampling Plan, and provide to EPA prior to implementation. Obtain EPA approval. Ensure that Items 3.1-3.6 are presented in site procedures or other documents and are adequately implemented.</p> <p>ii. Provide, for EPA evaluation, DTC codes, input parameters to the code, and the validity of any</p>

Enclosure B

Summary of Comments Suggesting Changes to WCPJP and Seeking Information from DOE and RH Sites

WC Elements	Revise the WCPJP or site specific documents to include the following:	Information from DOE ¹	Information from RH Waste Sites in site-specific documents
	<p>2. To describe the program by which the modeling process will be controlled</p> <p>3. To require implementation of either the EPA QAPJP guidance for Modeling or a similar set of guides</p> <p>4. To include an approach discussing application of quality requirements to the DTC modeling process</p> <p>5. To include a requirement for determination of LLD in DTC using a definition of the LLD that is analogous to and consistent with that specified in the NDA section (section 4.1.5.1 of WCPJP)</p> <p>6. To require that sites package in a given container only materials from the same waste stream, with similar radiological Properties</p>		<p>assumptions made in the code for each waste stream prior to its implementation, as well as any other information (procedures, etc) requested by EPA</p> <p>iii. Demonstrate that the DTC method provides results that meet data quality characteristics comparable to those that NDA systems must meet when characterizing the CH waste. If site-specific DTC QAOs are appropriate (see Item 3.a), obtain EPA approval of the approach prior to implementation at RH sites.</p> <p>iv. Document how values are derived from the activities of individual radionuclides and their associated uncertainty, including TRU alpha activity and its uncertainty for container activity in the event that individual drums are overpacked</p> <p>v. Require that personnel implementing the DTC method review all AK information pertinent to the DTC method</p> <p>vi. Check the dose rate measurement process to ensure that it conforms to the assumptions inherent in the shielding model producing the conversion factors</p>
4: DA	<p>1. Unless DOE can explicitly demonstrate that the following should be included in other documentation, revise the WCPJP or other documentation to:</p> <ul style="list-style-type: none"> • Address and define programmatic elements such 	<p>a. Provide written justification to EPA, for approval, if DOE determines it cannot include requirements in Item 4.1 in the WCPJP.</p>	<p>i. Prepare site specific Confirmatory Testing Plan to address DA activities, which will include the Sampling Plan; provide this to EPA prior to implementation. Obtain EPA approval. Also provide other information (e.g. procedures) as requested by EPA. Ensure that Item 4.1 is addressed. If requirements in Item 4.1 are not included in the WCPJP generate site specific</p>

Enclosure B
Summary of Comments Suggesting Changes to WCPIP and Seeking Information from DOE and RH Sites

WC Elements	Revise the WCPIP or site specific documents to include the following:	Information from DOE ¹	Information from RH Waste Sites in site-specific documents
	<p>programmatic elements such as allowable error, data validation criteria, data usability criteria, and data assessment specifications</p> <ul style="list-style-type: none"> • Provide sampling plan guidance to include sampling, analysis, data validation, data usability, and data assessment • Include more specific criteria and requirements addressing data uncertainties, validation, and usability criteria; as well as minimum performance standards • Clarify and define QC criteria: control limits for calibration activities, ICP-MS specific QC, chemical yields; and radionuclides in LCS and MS mixes and spike samples 		<p>not included in the WCPIP, generate site specific requirements. Obtain EPA approval of the approach prior to implementation at RH sites. RH sites must, for meet all DA requirements, for example, these sites must::</p> <ul style="list-style-type: none"> • Document process and results of random sample selection • Document process and results of control chart activities used to evaluate calibration and accuracy QAOs • Implement data management, validation, and usability criteria procedures • Produce DA batch data reports that document DA sample results and all QC results used to assess conformance to QAOs for precision, accuracy, representativeness, completeness, and comparability • Demonstrate that program level reviews of QAOs, as defined in the Confirmatory Testing Plan and/or Data Acquisition Plan, are performed and documented

Enclosure B
Summary of Comments Suggesting Changes to WCPIP and Seeking Information from DOE and RH Sites

WC Elements	Revise the WCPIP or site specific documents to include the following:	Information from DOE ¹	Information from RH Waste Sites in site-specific documents
5: AK	1. To include specific quantitative criteria for comparing data generated to confirm AK with the AK record (include in Attachment A of the WCPIP).		<p>i. Revise site documents to include quantitative criteria for comparing data generated to confirm AK with available AK prior to implementation</p> <p>ii. Demonstrate compliance of AK data with the quality characteristics of precision, accuracy, representativeness, completeness, and comparability when Peer Review or the QA Program qualification routes are selected.</p> <p>iii. Make available complete CRR and each available AK summary for EPA inspection. EPA shall determine the scope of the approval, in that approval of the CRR does not necessarily mean that all wastes with forthcoming CRRs may be approved.</p>
6: WWIS	1. Revise the WCPIP to show how RH data will be populated in the WWIS in a manner to ensure consistency and accuracy amongst sites	a. <i>Seek and acquire EPA approval of any modifications to WWIS fields or input decision criteria and WWIS User Guide to accommodate RH WC information</i>	i. Demonstrate adequate WWIS data entry/transmittal in conformance with Item 6.1.

1 – DOE activity that must continue to address after EPA approval of the RH program are presented in italics. All others presented occur prior to formal approval. Note that this column is not necessarily all inclusive, and EPA may identify additional elements not specified on this chart requiring continued DOE attention through the course of RH Program implementation.